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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,481	10/24/2003	Elazar Rabbani	ENZ-60(CIP)	2531
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ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/693,481	Applicant(s) RABBANI ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-624 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-624 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-31 and 145-147, drawn to a method for synthesizing a nucleic acid copy of at least one RNA target, classified in class 435, subclass 91.21.
 - II. Claims 32-61 and 145-147, drawn to a method for synthesizing a nucleic acid copy of at least one RNA target with applying at least one ribonucleotide analogue lacking a 3' OH group and modifying the RNA by adding the ribonucleotide analogue to the 3' end of the RNA target, classified in class 435, subclass 91.21.
 - III. Claims 62-119 and 145-147, drawn to a method for synthesizing a nucleic acid copy of at least one RNA target with applying at least one non-inherent UDT comprising nucleotide analogue lacking a 3' OH group at the 3' terminus and modifying the RNA by the addition of the UDT to the 3' end of the RNA, classified in class 435, subclass 91.21.
 - IV. Claims 120-147, drawn to a method for synthesizing a nucleic acid copy of at least one RNA target with at least one normal ribonucleotide and at least one ribonucleotide terminator and modifying the RNA by adding the ribonucleotide and the ribonucleotide terminator to the 3' end of the RNA, classified in class 435, subclass 91.21.

Art Unit: 1637

- V. Claims 148-161, drawn to a method for synthesizing a copy of at least one DNA target with modifying the DNA target by adding at least one ribonucleotide to the DNA target and treating the modified DNA target to render the 3' end of the modified DNA target unextensible, classified in class 435, subclass 91.2.
- VI. Claims 162-177, drawn to a composition of matter comprising a chimeric primer or chimeric nucleic acid construct comprising at least one deoxyribonucleotide and ribonucleotide at the 3' terminus, classified in class 536, subclass 24.3.
- VII. Claims 178-210, drawn to a composition of matter comprising a primer or nucleic acid construct wherein the primer or the nucleic acid construct comprises a set of permutational primers with a homopolymeric nucleotide sequence or promoter sequences and a substitute at 2' position of ribonucleotide, and a solid matrix, classified in class 536, subclass 24.3.
- VIII. Claims 211-250, drawn to a method for synthesizing at least one copy of a library of nucleic acid target, classified in class 435, subclass 91.2.
- IX. Claims 251-287, drawn to a method for synthesizing at least one copy of a library of nucleic acid target with adding a non-inherent UDT to an extended primers or an extended nucleic acid construct, classified in class 435, subclass 91.2.
- X. Claims 288-311, drawn to a method for synthesizing at least one copy of a library of nucleic acid target with a chimeric nucleic acid primer or chimeric nucleic acid construct comprising at least one deoxyribonucleotide and at least one ribonucleotide at the 3' terminus of the chimeric primer or the construct, classified in class 435, subclass 91.2.

- XI. Claims 312-339, drawn to a method for synthesizing at least one copy of nucleic acid target with template dependent reagents and template independent reagent, classified in class 435, subclass 91.2.
- XII. Claims 340-373, drawn to a method for synthesizing at least one copy of nucleic acid target with template dependent reagents and template independent reagent and at least one chimeric primer or chimeric construct comprising complementary sequence to a homopolymeric sequence in the nucleic acid target, classified in class 435, subclass 91.2.
- XIII. Claims 374-409, drawn to a method for synthesizing at least one copy of nucleic acid target with template dependent reagents and template independent reagent and at least one chimeric primer or chimeric construct comprising at least one deoxyribonucleotide and at least other nucleotide at 3' terminus of the primer or construct, classified in class 435, subclass 91.2.
- XIV. Claims 410-453, drawn to a method for synthesizing at least one copy of nucleic acid target with a set of permutational primers or nucleic acid construct, classified in class 435, subclass 91.2.
- XV. Claims 454-505, drawn to a method for synthesizing multiple copy of at least one nucleic acid with one forward primer or forward nucleic acid construct comprising at least one nucleotide at the 3' end of the primer or nucleic acid construct that inhibits or eliminates extension by a template independent polymerase and is a substrate for extension by a template dependent polymerase, classified in class 435, subclass 91.2.

- XVI. Claims 506-517, drawn to a method of synthesizing a double-stranded DNA copy from at least one RNA target in which a non-inherent UDT is added to the 3' end of the first cDNA copy, classified in class 435, subclass 91.52.
- XVII. Claims 518-537, drawn to a method for the amplification of a library of nucleic acids applying at least one first primer comprising a first UDT and at least one a second primer comprising a second UDT, classified in class 435, subclass 91.2.
- XVIII. Claims 538-549, drawn to a composition of matter comprising a set of nucleic acid constructs, classified in class 536, subclass 24.3.
- XIX. Claims 550-563, drawn to a method for adding nucleic acid sequences to a collection of target nucleic acids, classified in class 435, subclass 91.52.
- XX. Claims 564-577, drawn to a method for adding nucleic acid sequences to a collection of target nucleic acids in which the collection of the target is divided into two portions and the set of nucleic acid constructs is divided into a first subset and second subset, the first portion of the target is ligated to the first subset of the nucleic acid construct and the second portion of the target is ligated to the second set of the nucleic acid construct, classified in class 435, subclass 91.51.
- XXI. Claims 578-591, drawn to a method for adding nucleic acid sequences to a collection of target nucleic acids in which the collection of the target is ligated to a first subset of construct to form a first group and then the first group is ligated to a second subset of construct to form the collection of target nucleic acid with added nucleic acid sequence, classified in class 435, subclass 91.2.

XXII. Claims 592-602, drawn to a method for adding nucleic acid sequences to a collection of target nucleic acids in which a second set of nucleic acid construct is involved, classified in class 435, subclass 91.52.

XXIII. Claims 603-613, drawn to a method for adding nucleic acid sequences to a collection of target nucleic acids in which a first set of nucleic acid construct which is divided into a first subset and a second subset and a second set of nucleic acid construct which is divided into a third subset and a forth subset are used, the collection target nucleic acid is divided into two portions, the first portion is ligated to the first subset to the 3' end and the third subset is ligated to the 5' ends of the nucleic acid target to form a first group, classified in class 435, subclass 91.51.

XXIV. Claims 614-624, drawn to a method for adding nucleic acid sequences to a collection of target nucleic acids with a first set of nucleic acid construct divided into a first subset of nucleic acid construct, and a second subset of nucleic acid construct and a second set of nucleic acid construct divided into a third subset of nucleic acid construct and a forth subset of nucleic acid construct in which the collection of target nucleic acid is ligated to the first subset to the 3' ends and the third subset is ligated to the 5' end of the nucleic acid target, and then the second subset is ligated to the 3' end and the forth subset is ligated to the 5' end of the target nucleic acid targets to form a collection of nucleic acid with nucleic acid added to the 3' and 5' ends, classified in class 435, subclass 91.51.

2. The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1637

- a. Inventions VI-VII and XVIII and I-V, VIII-XVII and XIX-XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products groups VI-VII and XVII are drawn to a composition comprising chimeric primer or chimeric nucleic acid construct or a set of nucleic acid construct which are nucleic acid sequences and can be used in nucleic acid purification.
- b. Among the products groups VI-VII and XVII, Group VI is drawn to a composition of matter comprising a chimeric primer or chimeric nucleic acid construct comprising at least one deoxyribonucleotide and ribonucleotide at the 3' terminus and a solid matrix, Group VII is drawn to a composition of matter comprising a primer or nucleic acid construct wherein the primer or the nucleic acid construct comprises a set of permutational primers with a homopolymeric nucleotide sequence or promoter sequences and a substitute at 2' position of ribonucleotide, and a solid matrix, and Group XVIII is drawn to a composition of matter comprising a set of nucleic acid constructs without a solid matrix. Thus, they have different components. Therefore, they are different inventions.
- c. Inventions I-V, VIII-XVII and XIX-XXIV are distinct if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions as indicated in the grouping section, each group has different designs, modes

of operation, and effects. Group I does require any steps cited in Groups II-V, VIII-XVII and XIX-XXIV, for example Group II requires applying at least one ribonucleotide analogue lacking a 3' OH group and modifying the RNA by adding the ribonucleotide analogue to the 3' end of the RNA target, Group III requires applying at least one non-inherent UDT comprising nucleotide analogue lacking a 3' OH group at the 3' terminus and modifying the RNA by the addition of the UDT to the 3' end of the RNA, Group IV requires at least one normal ribonucleotide and at least one ribonucleotide terminator and modifying the RNA by adding the ribonucleotide and the ribonucleotide terminator to the 3' end of the RNA, Group V requires modifying the DNA target by adding at least one ribonucleotide to the DNA target and treating the modified DNA target to render the 3' end of the modified DNA target unextendable, Group VIII is for synthesizing at least one copy of a library of nucleic acid target which requires a library of nucleic acid targets, primer or nucleic acid construct comprising terminal nucleotide at the 3' end with substitutions on the 2' position of the ribose ring, Group IX is for synthesizing at least one copy of a library of nucleic acid target which requires adding a non-inherent UDT to an extended primers or an extended nucleic acid construct, Group X is for synthesizing at least one copy of a library of nucleic acid target which requires a chimeric nucleic acid primer or chimeric nucleic acid construct comprising at least one deoxyribonucleotide and at least one ribonucleotide at the 3' terminus of the chimeric primer or the construct, Group XI is for a method for synthesizing at least one copy of nucleic acid target which requires template dependent reagents and template independent reagent, Group XII is for a method for synthesizing at least one copy of nucleic acid target which additionally

requires at least one chimeric primer or chimeric construct comprising complementary sequence to a homopolymeric sequence in the nucleic acid target, Group XIII is for a method for synthesizing at least one copy of nucleic acid target which additionally requires one chimeric primer or chimeric construct comprising at least one deoxyribonucleotide and at least other nucleotide at 3' terminus of the primer or construct, Group XIV is for synthesizing at least one copy of nucleic acid target in which a set of permutational primers or nucleic acid construct is required, Group XV is for synthesizing multiple copy of at least one nucleic acid which requires one forward primer or forward nucleic acid construct comprising at least one nucleotide at the 3' end of the primer or nucleic acid construct that inhibits or eliminates extension by a template independent polymerase and is a substrate for extension by a template dependent polymerase, Group XVI is for synthesizing a double-stranded DNA copy from at least one RNA target in which a non-inherent UDT is added to the 3' end of the first cDNA copy, Group XVII is for the amplification of a library of nucleic acids applying at least one first primer comprising a first UDT and at least one a second primer comprising a second UDT, Group XIX is for adding nucleic acid sequences to a collection of target nucleic acids which requires a set of nucleic acid constructs and in which the set of nucleic acid construct is ligated to the target nucleic acids, Group XX additionally requires that the collection of the target is divided into two portions and the set of nucleic acid constructs is divided into a first subset and second subset, the first portion of the target is ligated to the first subset of the nucleic acid construct and the second portion of the target is ligated to the second set of the nucleic acid construct, Group XXI

additionally requires the collection of the target is ligated to a first subset of construct to form a first group and then the first group is ligated to a second subset of construct to form the collection of target nucleic acid with added nucleic acid sequence, Group XXII additionally requires a second set of nucleic acid construct, Group XXIII additionally requires that a first set of nucleic acid construct which is divided into a first subset and a second subset and a second set of nucleic acid construct which is divided into a third subset and a forth subset are used, the collection target nucleic acid is divided into two portions, the first portion is ligated to the first subset to the 3' end and the third subset is to the 5' ends of the nucleic acid target to form first group, Group XXIII additionally requires that a first set of nucleic acid construct which is divided into a first subset and a second subset and a second set of nucleic acid construct which is divided into a third subset and a forth subset are used, the collection of target nucleic acid is divided into two portions, the first portion is ligated to the first subset to the 3' end and the third subset is ligated to the 5' ends of the nucleic acid target to form a first group, Group XXIV additionally requires that a first set of nucleic acid construct divided into a first subset of nucleic acid construct, and a second subset of nucleic acid construct and a second set of nucleic acid construct divided into a third subset of nucleic acid construct and a forth subset of nucleic acid construct are used in which the collection of target nucleic acid is ligated to the first subset to the 3' ends and the third subset is ligated to the 5' end of the nucleic acid target, and then the second subset is ligated to the 3' end and the forth subset is ligated to the 5' end of the target nucleic acid targets to form a collection of nucleic acid with nucleic acid added to the 3' and 5' ends.

Art Unit: 1637

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1637

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung
March 31, 2006


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

4/3/06